Supreme Court, U.S.
FILED
OCT 29 2002
CLERK

No. 02-606

IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS
INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the Eighth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether this Court should grant certiorari to review the unanimous three-page per curiam affirmance of a jury verdict for breach of contract based on unique facts in a diversity case applying Connecticut law.

2. Whether under Connecticut law a party who drafted a contract can avoid the consequences of his breach by arguing that he would have chosen to perform the contract in an illegal manner.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Biomedical Systems Corporation states that it is a privately-held corporation with no parent corporation and that no publicly-held company holds any portion of its stock.

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STATEMENT OF THE CASE

The Question supposedly Presented by GE's petition is hypothetical, is not framed by the record in this case, and is predicated on "facts" that are contrary to the evidence. It asks the Court to decide what *would have happened* if GE had not breached its contract and in the course of performance had chosen allegedly to violate applicable laws and regulations. No manufacturer "sought" FDA action by submitting a "false application." Liability was imposed here by a Missouri jury for breach of contract under Connecticut law because GE unilaterally decided to disregard a provision in a written, integrated Agreement between the parties in favor of a regulatory process GE deemed more desirable — which ultimately took 3½ years.

The petition does not mention the constantly-changing excuses for its flagrant breach that GE offered during the course of this litigation, culminating with the implausible last-ditch assertion that the contract — which GE drafted — is "illegal." Both lower courts analyzed the contract under Connecticut law and quite reasonably held that it was enforceable because it did not have "a violation of law as its inherent purpose" and did not require acts which are prohibited by statute. *See Haynes Constr. Co. v. Cascella & Son Constr., Inc.*, 647 A.2d 1015, 1020-21 (Conn. App. 1994); *Burns v. Koellmer*, 527 A.2d 1210, 1213 (Conn. App. 1987). There was abundant evidence that GE could easily have honored its promise to Biomedical without violating any law or regulation.

Hence, petitioner's Question Presented is based on a hypothetical, non-existent scenario and is contradicted by abundant evidence accepted by the jury. Accordingly, we will review that evidence to place the petition in its proper context.

The Parties

Respondent Biomedical Systems Corporation is a family-owned Missouri corporation headquartered in St. Louis. It is engaged in the medical monitoring business, both cardiovascular and obstetrical.

Petitioner GE Medical Systems Information Technologies, Inc. is a wholly-owned subsidiary of General Electric Corporation. It is the successor to Marquette Medical Systems, Inc., which GE acquired in 1998, and to Corometrics Corporation, which Marquette acquired in 1997. Unless the context requires otherwise, we will refer to all of these entities as "GE" or "petitioner."

The HUAM Industry and 510(k) Clearance

This diversity case involves equipment used in the field of home uterine activity monitoring ("HUAM"). Hospitals and clinics have used uterine activity monitors since the 1960s to detect contractions either during labor or earlier if a pregnant patient is hospitalized with complications, such as pre-term labor. A HUAM is a portable version of the hospital-based monitor. The manufacturer simply adds a telephone modem to the device so that it can transmit data on contractions, fetal movement, and other uterine activity over telephone lines. This allows prescribing physicians to have access to critical information without admitting the patient to the hospital. The monitors, whether hospital-based or portable, cannot harm the patient and are used the same way whether a patient is pre-term or at term.

Since 1984, thirteen different HUAMs have been given clearance for marketing by FDA under its "510(k)" procedure. This 510(k) nomenclature is a shorthand reference to the speedy clearance process provided under §510(k) of the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §360(k). FDA's formal name for the

510(k) process is "Premarket Notification." Section 510(k) allows a manufacturer to give FDA 90 days' advance notice that it intends to market a medical device that is substantially equivalent to another legally marketed device already cleared by FDA, including for the same use. If FDA agrees that the new device is substantially equivalent to the "predicate device," it then issues a 510(k) clearance letter to the manufacturer allowing it to market the device.

This Court noted in *Medtronics, Inc. v. Lohr*, 518 U.S. 470 (1996), that the 510(k) process is demonstrably faster than the more rigorous pre-market approval (PMA) procedure. A PMA review takes about 1200 hours, whereas a 510(k) review takes about 20 hours and is completed within 90 days. *Id.* at 478-79. Approximately 80% of new devices have been introduced into the market through the 510(k) process and without PMA review. *Id.* As the Court observed, "the 510(k) process is focused on equivalence, not safety." *Id.* at 493.

In 1990, GE's predecessor, Corometrics, decided to enter into the HUAM business. Corometrics obtained clearance to market its Model 600 through a 510(k) application it submitted to FDA. Even though Corometrics knew that its device would be used in connection with a pre-term birth prevention program, it filed an application with a "statement of intended use" that stated:

> "The Model 600 Uterine Activity Monitor is intended for home uterine activity monitoring of patients at term, *but is not intended for prediction of pre-term labor*. Both the device top panel and the Operations Manual are clearly labeled to this effect."

FDA cleared the Model 600 in 90 days but, as with other HUAMs, required Corometrics to affix a label stating:

> "Warning: Not to be used for prediction of pre-term labor as this use is considered investigational."

Off-Label Use

FDA began regulating medical devices in 1976. It does not regulate the practice of medicine, however, and cannot prevent physicians from using an approved medical device or drug for non-FDA-approved uses if the physician believes it will be helpful to the patient. Thus, even though uterine activity monitors were cleared by FDA for term use in hospitals and clinics, physicians could prescribe the monitors for pre-term use in the home setting. From a medical standpoint, the term and pre-term uses are really the same: they measure contractions.

A physician's prescription of equipment for uses not yet approved by FDA is called "off-label" use. Such off-label use is common throughout the practice of medicine. Most major insurance companies pay for HUAM monitoring for patients in high-risk pregnancies without regard to whether the physician has prescribed the monitor on- or off-label.

Biomedical developed its entire HUAM business using "AMS" monitors. AMS had obtained 510(k) clearance for its monitor by notifying FDA that its monitor was substantially equivalent to earlier monitors cleared for term use. The AMS monitors contained the same limiting label as Corometrics Model 600. The presence of the label did not inhibit physicians from prescribing the monitor to high-risk pregnant women for pre-term use. Still prescribed today for a variety of indications, the aging AMS monitor is 510(k) cleared only for term use.

In 1993, Biomedical sought to upgrade its monitoring equipment and decided to develop its own HUAM. Biomedical's new monitor was near completion by early 1996. The device was easier to use, transmitted data faster, and unlike the AMS, was Y2K compliant. In April 1996, Biomedical's chairman and his son met in Connecticut with representatives of petitioner to discuss a possible joint venture for the manufacture and marketing of the new monitor, christened the Model 770. Biomedical made it clear at that meeting that its participation was conditioned upon applying for and obtaining 510(k) clearance to take advantage of a "window of opportunity" in the marketplace. They were told by a top GE executive, "Don't worry, I'll take care of it."

The Technology Transfer Agreement

The contract in issue in this case, the Technology Transfer Agreement between Biomedical and GE dated January 28, 1997 ("Agreement"), was drafted by petitioner's lawyers. It required Biomedical to transfer its technology to petitioner, which in turn agreed to manufacture and sell the device to Biomedical at a discount. Petitioner also agreed to pay Biomedical a royalty on all other sales. Biomedical was precluded from selling the monitor.

Petitioner was charged with the contractual duty of obtaining regulatory approval. The Agreement in five different paragraphs used the term "510(k)" seven times; no other type of regulatory approval was mentioned. In paragraph 8, it provided that "Corometrics agrees that it will bear the full cost of the 510(k) submission. . . ." The Agreement also stipulated that it "shall be construed in accordance with the substantive laws of the State of Connecticut" (¶17).

The Breach

Despite the language of the Agreement, GE advised Biomedical in March 1997 that it had decided to pursue a different regulatory approval process called reclassification, rather than 510(k) clearance. As soon as he learned of the change in strategy, Biomedical's chairman called GE to protest. He was told that reclassification would take only a little longer than 510(k) clearance and that GE would provide sufficient monitors in the meantime to serve Biomedical's clientele. Neither promise was fulfilled.

In June 1997, petitioner submitted its reclassification petition pursuant to §513(f) asking FDA to reclassify HUAM monitors from Class III to Class II for preterm use only for a narrowly-defined patient population: women who had experienced prior pre-term deliveries. Petitioner never intended to limit the use of the device to women with a prior pre-term birth. Fewer than ten percent of the prescribed patients have had prior pre-term deliveries.

The reclassification petition was filed under §513(f), and no part of it purported to be filed under §510(k). When reclassification was ultimately granted in January 2001 — 3½ years later — FDA confirmed that no 510(k) application had been submitted and stated: "You do not need a 510(k) premarket notification."

GE gave varying reasons for seeking reclassification rather than 510(k) clearance. Until late in this lawsuit, however, it was never suggested to Biomedical that the reason for pursuing reclassification was that the pursuit of 510(k) clearance would be illegal. To the contrary, Maria Fouts, GE's regulatory guru, stated precisely the opposite in an internal memorandum:

> "As [I've told] you before, there is nothing barring us from submitting a 510(k) for term use. We are just limited to 'Term use' claims (e.g. in promotional brochures, literature, op manuals, etc.). . . .
>
> "I would presume that if we chose to file a 510(k) for the Model 770 the action that AMS took would be required of us. The benefit is that you have a product that you can legally market in the U.S. regardless of the petition, albeit with limited claims."

There was no evidence that anyone proposed to market the 770 monitor for pre-term use. Biomedical always understood that, after obtaining 510(k) clearance, the monitor would be labeled as cleared for term use only and that all of the promotional brochures, operational manuals, and other literature describing the monitor would avoid pre-term references. These limitations would be nothing new to Biomedical or GE, since the AMS monitor and the Model 600 that they had used, respectively, for years had the same labeling and limitations in their marketing materials.

Ultimately, rather than obtaining clearance to market the device by the summer of 1997, GE received reclassification for very limited pre-term use in January 2001. By the time the monitors became available, the entire marketing opportunity which provided the basis for the Agreement had evaporated.

Proceedings Below

Biomedical filed this action on October 8, 1999 in the United States District Court for the Eastern District of Missouri. Jurisdiction was based on diversity of citizenship under 28 U.S.C. §1332. GE filed an answer which included three affirmative defenses, none of which was illegality. GE's position from the outset of

the case was that the contract was ambiguous and that it contemplated a two-step process whereby it would first obtain a reclassification and later get 510(k) clearance. Its initial answer, which was on file for well over a year, simply suggested that Biomedical's interpretation of the supposedly "ambiguous" contract was "inconsistent" with the FDA regulations.

Nearly a year after the lawsuit was filed, GE moved to dismiss, alleging for the first time that the contract was illegal. The district court denied that motion in an unreported order. The trial began on March 19, 2001, and continued for 16 trial days. The district judge, having ruled the contract legal, rejected repeated efforts by GE to explain why it decided, after the Agreement was signed, that it was more appropriate, desirable, or "legal" to pursue reclassification rather than 510(k).

Biomedical presented expert testimony that it was damaged to the extent of $135,379,873 by reason of the 3½-year delay caused by GE's unilateral departure from the regulatory pathway specified in the contract.

The case was submitted to the jury on Biomedical's claims of breach of contract and fraud. On April 9, 2001, the jury returned a unanimous verdict against GE on the contract claim only and awarded Biomedical actual damages of $75,000,000. GE appealed to the Eighth Circuit, which heard oral argument on April 16, 2002. On April 23, 2002, a three-judge panel of the Court of Appeals with a combined 91 years of judicial experience unanimously affirmed the judgment in a three-page per curiam opinion that summarily rejected GE's "illegality" theory. The court concluded, based on the parties' familiarity with the record, "that an extended opinion in this diversity case would serve no useful purpose" (Pet. Apdx 1a). The entirety of its holding on

illegality comprises two sentences:

> "[W]e conclude the district court properly denied GE judgment as a matter of law on its illegality defense. In our view, the contract unambiguously required GE to apply for 510(k) clearance and did not require GE to violate federal law." *Id.* at 2a-3a.

GE's petition for rehearing and rehearing en banc was denied without a recorded dissent. *Id.* at 7a.

REASONS FOR DENYING THE PETITION

This is a garden-variety breach-of-contract case that found its way into federal court because the parties were of diverse citizenship. The ultimate state-law question framed by the distinctive facts in this litigation is whether the Agreement could be performed without the commission of an illegal act. The four federal judges who have examined this question had little trouble in concluding that GE's belated excuse for nonperformance — its "illegality" defense — was entirely bogus.

The decision below has none of the earmarks of certworthiness. It is so cryptic as to not permit of the ominous extrapolations predicted by the petition. In contrast to its characterization here, GE complained in its rehearing petition below about the "panel's failure to explain the basis for [its] decision. . . ." This case is uniquely dependent on its facts, which are not evident from the Court of Appeals opinion, and which not even GE pretends are commonplace or likely to recur. There is no conflict with any other judicial decision or with a proper reading of the governing statutes and regulations. Despite GE's overblown rhetoric, this case is not about safety. The 770 monitor poses no health risk whether it is used at 18 weeks, 28 weeks, or 38 weeks, and GE never uttered a word about safety at trial.

Finally, GE's extensive reliance on an FDA amicus brief filed several years ago in a different context bespeaks the dearth of meaningful authority supporting petitioner's position.

I. GE'S LATE-CONCEIVED "ILLEGALITY" DEFENSE IS BASELESS.

GE's original answer did not plead illegality; it merely stated that Biomedical's interpretation of the Agreement was "inconsistent" with the FDCA, regulations, and guidelines. Once GE's trial counsel realized the magnitude of the problem they were facing, the illegality theory was hatched and became the basis for defendant's motion to dismiss, which was filed almost a year after the lawsuit began.

Whether a contract is legal or illegal is obviously a question of law for the court. *Kaiser Steel Corp. v. Mullins*, 455 U.S. 72 (1982). Here, both lower courts quickly and astutely recognized that GE's illegality defense was specious. Every manufacturer in the HUAM industry — including GE itself — has a monitor that was cleared by FDA for term-use marketing pursuant to §510(k), despite common knowledge that HUAMs were often legally prescribed "off-label" for pre-term monitoring. The Agreement required GE to do nothing different from what it and other manufacturers had previously done to obtain 510(k) clearance for HUAMs.

A. This Case Is Not About Health or Safety.

GE's repeated references to health, safety, "extremely dangerous" medical devices, and potentially "disastrous results" are certified red herrings. There was no claim at trial — and no evidence — that a HUAM poses any health or safety threat to mother or fetus at *any* gestational age. Additionally, apart from the fact that

this case has never involved health or safety, both Congress and this Court have noted the limited role of §510(k) as a labeling provision and have required FDA to allow competition in the marketplace by giving quick-path marketing permission to follow-on manufacturers whose devices are substantially equivalent to already-cleared devices. FDA is more than able to root out health and safety problems, but where, as here, 13 other monitors have previously been cleared, the health and safety determination has already been made.

Furthermore, FDA has plenty of statutory ammunition to pursue manufacturers who promote products or devices for purposes for which they were not cleared. Such devices are deemed adulterated or misbranded under 21 U.S.C. §§ 331 or 351 and are subject to forfeiture and other sanctions.

Contrary to GE's florid embellishments, nothing in the Court of Appeals opinion serves as a road map for regulatory skullduggery. The opinion assumes familiarity with the underlying facts and is of no utility to a stranger to the record. The decision in this case does not purport to interpret any statutes or regulations and has no effect on FDA's ability to perform its Congressionally-mandated duties.

B. The Role of "Intended Use" in the 510(k) Process

GE's illegality argument boils down to the contention that an applicant for 510(k) clearance violates federal law if its "statement of intended use" does not include all potential uses of the device that it anticipates any person will engage in. GE's proferred excuse for breaching its contractual obligations thus embodies a badly distorted view of the regulatory process.

As GE acknowledges (Pet. 5), the manufacturer of the

device (here, GE) can establish that its device is "substantially equivalent" to an already-cleared predicate device if it has the same intended use as the predicate device. §360c(i)(1)(A). The intended use is the use for which the applicant is seeking clearance, and the only requirements are that the device is suitable for that use and that the applicant intends to limit its labeling and promotional efforts to that use.

Even if the manufacturer knows that the device will be prescribed by physicians for uses other than those labeled and promoted, it is not required to identify such uses as long as it does not plan to promote or market the device for those uses. As FDA told this Court in its amicus brief in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001):

> "Under the regulations, a manufacturer is not required to disclose every foreseeable use of a device that it secretly desires. Physicians often use medical devices for purposes that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market." Brief of United States as Amicus Curiae, No. 98-1768, p. 15.

FDA further advised the Court that as long as the stated intended use is *bona fide*, the application would be false and misleading only if "at the time of the application a manufacturer plans to *promote and distribute* a device *exclusively*" for a use that is not disclosed. *Id.* (emphasis added). Hence the duty to reference an intended use in a 510(k) submission, by FDA's own declaration, is triggered by the manufacturer's planned *promotion*, not knowledge or anticipation, of an intended use. There is no evidence

in the record that either of the parties planned to promote the 770 monitor for pre-term use.[1]

According to §360c(i)(l)(E)(i), "any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k)." Thus, Congress has mandated that at the application stage the intended use of a device is to be determined from the face of the request for 510(k) clearance, not from §801.4 of the regulations cited by GE (Pet. 6), or any other source. That is, for the purpose of 510(k) *clearance*, the intended use of a medical device simply is that specific proposed use for which the manufacturer claims substantial equivalence to a "predicate" device already in the marketplace.

GE argued below that §360c(i)(1)(E)(i) does not apply to this case because it was enacted in 1997 after the Agreement was signed. The legislative history reveals, however, that it reflects Congress's intent from the inception of the Medical Device Regulation Act ("MDA") in 1976. *See* S. Rep. No. 105-43, at 60 (1997). The Senate Report further explains that the section was meant to clarify Congress's long-standing intention that the FDA "not exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration." *Id.*

In direct contrast to GE's argument based on the

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[1] GE's statement that "Biomedical promotes its monitoring services as appropriate for home use by pre-term women" (Pet. 11) is misleading. Biomedical's promotional materials introduced at trial describe a broad range of diagnostic and educational services it can provide in a pre-term birth prevention program. Such techniques may include self-palpation and nurse follow-up. Biomedical's materials most certainly made no pre-term claims or representations regarding the 770 monitor.

inapplicable §801.4, Congress pointed out that in the MDA:

> "Congress intended that device classification and approval decisions be made on the intended use of devices as described in labeling. Over the years, FDA has made pre-market regulatory decisions based on uses for devices that are unrelated to the intended uses set forth in labeling....
>
> "For pre-market notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or substantially similar to the intended use of a predicate device, then the device may be found sufficiently equivalent to the predicate. No considerations outside of the proposed labeling for the 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device." *Id.* at 60-61.

GE is misusing §801.4. It is a *labeling* regulation unrelated to the 510(k) regulatory provisions. *See* 21 C.F.R. Part 801 (Labeling) as compared to 21 C.F.R. Part 807, Subpart E (Premarket Notification Procedures). By its own terms, §801.4 defines "intended use" only for purposes of "§§801.5, 801.119 and 801.122," none of which deal with premarket notification. To further dispel any doubt that §360c of the statute, and not §801.4, is the proper source for the meaning of "intended use" in this case, the Ninth Circuit has determined that "[t]he 'intended use' inquiry for determining 'substantial equivalency' focuses . . . on whether the intended use of the product is *similar* to that of a preexisting, legally marketed device." *United States v. Bowen*, 172 F.3d 682, 687 (9th Cir. 1999). The court concluded that §360c contains the definition of "in

tended use" for the purpose of 510(k) clearance, while citing regulation §801.4 as an example of a provision relevant only "*[i]n other circumstances*, [where] courts can continue to look beyond the product's label." *Id.* (emphasis added).

GE's suggested interpretation of "intended use" is misconceived for another reason. As its own reclassification petition reveals, the *only* intended use described by GE in that petition was the intent "to measure the duration, frequency, and relative pressure of uterine contractions in a home or outpatient environment." Precisely the same statement could be made regarding *any* HUAM, no matter what gestational age is involved, and there is no reason why the same statement by GE in a 510(k) submission would have been anything but completely accurate.

Using GE's own interpretation of "intended use," the "intended use" of an HUAM is always the same — it is only the patient population (or indications for use) that changes. The monitor is used always and only to measure contractions, whether the patient has completed 34, 36, or 38 weeks. Hence, even if the targeted patient group were misdescribed, that would not constitute a false statement of an "intended use" as defined by GE.

C. FDA Has No Authority to Deny 510(k) Clearance Based on Concerns About "Off-label" Use by Physicians.

Confining FDA's inquiry to "substantial equivalence" is consistent with the recognition that FDA has no jurisdiction to regulate the practice of medicine and that devices cleared for one use are often prescribed by physicians for different (or "off-label") uses. Congress has codified this limitation on FDA's jurisdiction in 21 U.S.C. §396: "Nothing in this Act shall be construed to

limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."

In *Buckman* this Court took note of the prevalence and acceptability of off-label use of devices cleared under 510(k). The Court again emphasized that the 510(k) process "requires only a showing of substantial equivalence to a predicate device" and observed that "... 'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." 531 U.S. at 348, 350.

The Court explicitly recognized the desirability of allowing manufacturers to apply for 510(k) clearance of medical devices for one use, while knowing that they would be prescribed for other uses by doctors, as one reason for prohibiting private fraud-on-the-FDA claims:

> "Would-be applicants may be discouraged from seeking 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates... to unpredictable civil liability." *Id.* at 350.

The *Buckman* opinion twice cites an article by Beck & Azari, "FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 FOOD & DRUG L.J. 71 (1998), in which the authors point out that courts, several states, and "FDA itself recogniz[e] the value and propriety of off-label use" and that "[o]ff-label use is widespread in the medical community and often is essential to giving patients optimal medical care,

both of which medical ethics, FDA, and most courts recognize." *Id.* at 72, 76-77.

FDA itself has testified before Congress that "FDA recognizes that, in certain circumstances, off label uses ...can be of great value. Some off-label uses have been of great historical importance." *Hearing Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight*, 104th Cong., 2d Sess. 61-62 (Sept. 12, 1996) (statement of Michael Friedman, Deputy FDA Commissioner). And the agency has repeatedly and consistently reaffirmed the value, propriety, and legality of off-label use. *See* 59 Fed.Reg. 59,820 (Nov. 18, 1994); 52 Fed.Reg. 8798 (Mar. 19, 1987); 48 Fed.Reg. 26,720 (June 9, 1983); 40 Fed.Reg. 15,392, (Apr. 7, 1975); 37 Fed.Reg. 16,503 (Aug. 15, 1972). "It is not the [FDA's] policy, intent, or bias to indicate that off-label uses are wrong, improper, or even investigational." *GAO Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate, Off-Label Drugs* at 11 (1991).

At trial, Dr. John P. Elliott, perhaps the foremost obstetrician in the country dealing with high-risk multiple pregnancies, told the jury that he regularly uses HUAMs for detection and treatment of pre-term contractions and that *all* the drugs he uses to discourage premature labor are off-label. He said that "the FDA actually totally supports this use of off-label indications for an approved drug" and that off-label use "is what I do for a living. So it's absolutely what is done in this country today." Dr. Elliott has used HUAMs on more than 1500 patients as a "useful tool" to help prevent prematurity and has never had an issue arise over such usage.

Thus, the role of FDA in reviewing 510(k) submis

sions, apart from the technology evaluation, is simply to determine whether the proposed marketing and promotional uses are substantially equivalent to those of another device already in the marketplace. FDA may not deny 510(k) clearance based on a concern that the device may be used off-label by the medical community, but it may deal with that concern by requiring the manufacturer to specify the limitations on use of the device. The line of demarcation under the statute is clear: FDA dictates label requirements; doctors practice medicine.

D. FDA's Treatment of Previous 510(k) Applications for HUAMs

Before GE and Biomedical signed the Agreement in January 1997, the market was being served almost exclusively by some of the 13 HUAMs previously cleared for term use under 510(k). Of special significance is the fact that GE's predecessor Corometrics (the signatory to the contract with Biomedical) had applied for and received 510(k) clearance for its Model 600 in 90 days in 1990.

Despite repeated denials by GE that the Model 600 was ever sold commercially, the evidence unmistakably established that at least $100,000 worth of those monitors were sold for use in pre-term evaluation. GE has never turned itself in to the U. S. Attorney as a result of these facts, nor has it offered to refund any of its would-be "ill-gotten" gains. For its part, Biomedical was using the AMS monitor in servicing patients for whom it was prescribed, and that device was regularly prescribed for pre-term ("off-label") use by obstetricians around the country. All its competitors also had monitors in the marketplace that had received quick-path clearance under 510(k). There was nothing "pretextual" about any of those 510(k) applications, and

FDA has never asserted that any HUAM was adulterated or misbranded.

It was against this backdrop that the parties agreed to do what GE had done before in order to get the improved 770 monitor to market while the window of opportunity was open. Biomedical simply wanted the same treatment for the 770 monitor that all competing products had received; and an internal memo from GE's senior regulatory affairs specialist acknowledged "there is nothing barring us from submitting a 510(k) for term use."

Confronted with a marketplace rife with 510(k)-cleared HUAMs being used by physicians for pre-term diagnosis, and relegated to a trumped-up "illegality" defense because of its obvious failure to perform a contractual undertaking, GE struggled at trial to suggest that the "regulatory climate" had changed at FDA after 1992. GE's statement that no HUAMs were 510(k)-cleared after 1992 (Pet. 9) ignores the fact that no 510(k) applications were *filed* during that period. And the 1999 panel report, upon which GE relies so heavily (and which was never sent to Biomedical), does not reflect a change of official policy but merely confirms that the 510(k) process is not available for pre-term *promotion*. Even if, as GE argues, FDA "invited" HUAM manufacturers to apply for reclassification, FDA had no discretion to reject a proper 510(k) application limited to term-use marketing. GE was bound by its contractual promise and was not free to follow a different route merely because its regulatory people wanted to curry more favor with the regulators. There was no change in the applicable statutes or regulations under which 13 other HUAMs had been 510(k) cleared. On the contrary, the enactment of §396 and the passage of §360c(i)(1)(E) in 1997 confirmed that Congress wanted

FDA to stick to its knitting and not become a policeman against off-label use.

E. GE Could Have Applied For — and Undoubtedly Would Have Received — 510(k) Clearance for Term Use Without Committing any Illegal Act.

All GE had to do to obtain 510(k) clearance for the 770 monitor was to show FDA that the 770 was substantially equivalent to other devices already legally marketed for term use. *That fundamental fact is undeniably true.* Such a statement of intended use — coupled with appropriate labeling disclaiming approval for preterm use — was precisely the approach followed by FDA in clearing at least 13 previous HUAMs pursuant to 510(k). The agency's action in those cases confirms the vacuity of GE's attempt to avoid the consequences of its breach by a *post-hoc* plea of illegality. Could FDA sponsor prosecution in 1997 for the same acts by the same party (and 12 others) it had blessed previously? *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43, 57 (1983) (agency changing its course must supply reasoned analysis, and agency action is arbitrary and capricious if agency has relied on factors which Congress has not intended it to consider).

If GE, as the manufacturer, had been truly concerned about the accuracy or "legality" of a statement of intended use identifying term patients only, then GE's proper course of action would *not* have been to break its promise to Biomedical but simply to limit its own marketing, labeling, and promotion to term use, as it had previously done with its Model 600. Moreover, under ¶ 12 of the Agreement, GE had a veto over any proposed "product labeling, literature and advertising" of the monitor and thus could have controlled Biomedical's promotional activities. But GE had no

cause for concern because Biomedical was willing to comply with any restrictions attached to 510(k) clearance, as it was already doing with regard to the AMS monitor. As stated previously, there was no evidence that anyone intended to promote or market the 770 for pre-term use.

GE could have fulfilled its contractual undertaking without saying anything even arguably false. It is no answer for GE to say that it did not intend to market the 770 for term use. It had agreed with Biomedical to apply for 510(k) clearance, and if that required GE to limit its promotion to term use, it had a contractual obligation to do so. A party cannot avoid its contractual obligations by arguing that it would have chosen to perform them in an illegal manner.

Finally, GE's illegality argument backfires because its own reclassification petition sought Class II treatment for pre-term patients *only if they had previously experienced a pre-term delivery*. The FDA Reclassification Order finally received in January 2001 therefore was limited to use for "Women with a clinical history of previous pre-term birth . . . . [Y]ou may not label or promote this monitor for any other indication for use." This category of permitted use encompasses fewer than 10% of all applications for which monitoring might be appropriate. The most common risk factors, such as multiple gestation, are still off-label. So, according to GE's logic, since it anticipated that physicians would prescribe the 770 for multiple gestation — by far the most pervasive use — its FDA filing was just as "false" as if it had been limited to term use. GE is thus ensnared by its own disingenuous advocacy.

F. A Claim of Illegality by the Party Who Drafted the Agreement Should Be Viewed Skeptically.

The irony and distastefulness of a party to a contract seeking to avoid its obligations by claiming it had agreed to break the law have not escaped judicial attention. In *Kelly v. Kosuga*, 358 U.S. 516, 519 (1959), the Court noted the observation in *McMullen v. Hoffman*, 174 U.S. 639, 669 (1899): "It has been often stated in similar cases that the defense [of illegality] is a very dishonest one, and it lies ill in the mouth of the defendant to allege it . . . ." The Court cautioned that "the federal courts should not be quick to create a policy of nonenforcement of contracts beyond that which is clearly the requirement of [a particular federal statute]." 358 U.S. at 519.

The remark from *McMullen* is especially apropos here. GE drafted the Agreement in which it promised Biomedical to do something that GE itself and many others had done before with agency approval. GE's own regulatory specialist admitted that "there is nothing barring us from submitting a 510(k) for term use." GE never took the position that its promise was illegal until it was faced with irrefutable evidence of a breach and had no other hole to crawl into. But neither the subject matter of the contract nor the consideration given required the commission of an act that could be deemed unlawful.

In sum, GE's promise to seek 510(k) clearance for the 770 monitor for term use was not illegal under Connecticut law. A statement that the monitor was substantially equivalent to other devices already on the market for term use would have been completely true, and at least 10% of the anticipated use was at term. The purpose of the 510(k) submission was to enable FDA to

determine only whether GE's stated intended use was substantially equivalent to the intended use of another device already in the market.

Furthermore, a statement that a HUAM was intended for term use would not be false unless the applicant had no intent whatsoever that monitors would ever be used by expectant mothers past their 36th week or, conversely, as phrased by FDA, unless they were marketed and promoted "exclusively" for pre-term use. And since FDA's role in processing 510(k) submissions is confined to determining "substantial equivalence" to existing devices, a failure to list legitimate off-label intentions of physicians would not be "material" to the agency's function, as required for a criminal offense.

GE has pointed to no case — and we have found none — where a 510(k) applicant has ever been charged with a criminal offense based on a statement of intended use.[2] In light of the prevalence and legality of off-label use, which is well known to and actually anticipated by FDA, any such prosecution would be ill-founded and in bad faith. And the medical, pharmaceutical, and medical device communities would surely be shocked and outraged by such action, especially considering the literally millions of off-label prescriptions written daily.

II. THE DECISION BELOW DOES NOT CONFLICT WITH ANY OTHER DECISION.

GE tries to conjure up a circuit conflict by invoking the decision in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev'd sub nom. Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341

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[2] The unsuccessful prosecution in *United States v. Barile*, 286 F.3d 749 (4th Cir. 2002), was not based on an intended use statement but on an allegedly false statement that the proposed device had been properly tested.

(2000). That was a class action by thousands of individuals claiming that the defendant had committed fraud on the FDA in connection with 510(k) clearance for orthopedic bone screws. After the district court had sustained a Rule 12 motion to dismiss, the Third Circuit, in a 2-1 "narrow" decision, reversed, holding that fraud-on-the-FDA claims should not be dismissed at the pleading stage and were not pre-empted by the MDA. 159 F.3d at 829.

GE's reliance on *Orthopedic Bone Screw* for a conflict is misplaced for a number of reasons: (1) that case arose in a completely different setting — thousands of multidistrict tort cases before the court on the pleadings in a pre-emption context, rather than, as here, a solitary private contract case after a three-week jury trial; (2) the statements by the Third Circuit relied on by GE were dicta not encompassed within the court's "narrow" holding; [3] and (3) the Third Circuit's judgment was reversed outright by this Court in *Buckman*, not "on other grounds," as GE suggests. The statements relied on by GE from the Third Circuit opinion were central to that court's view of the law, which was completely overturned by this Court. The Court of Appeals' premises fell with its conclusion, and the Third Circuit opinion is a nullity that affords no basis for asserting an inter-circuit conflict.[4]

Moreover, as pointed out earlier, this Court expressly endorsed off-label use and refused to permit fraud-on-the-FDA claims based on off-label use because:

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[3] Indeed, the alleged "holding" quoted on page 15 of the petition is actually nothing but a recitation of the plaintiffs' allegations. *See* 159 F.3d at 828.

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[4] Apparently for these reasons, *Orthopedic Bone Screw* was not even cited in GE's opening brief in the Eighth Circuit.

"Would-be applicants may be discouraged from seeking 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates... to unpredictable civil liability." *Buckman*, 531 U.S. at 350.

III. GE'S RELIANCE ON FDA'S AMICUS BRIEF IN *BUCKMAN* IS INAPPROPRIATE AND, IN ANY EVENT, PRESENTS NO ISSUE WORTHY OF THIS COURT'S REVIEW.

Devoid of any case law supporting its position, GE adopts a decidedly unorthodox approach by relying extensively on an amicus curiae brief filed by an administrative agency in another case where its processes were directly involved and where the Court expressly requested its participation. GE's reliance on the FDA amicus brief in *Buckman* is unavailing and at most asks the Court to apply its prior decision in *Auer v. Robbins*, 519 U.S. 452 (1992), to the esoteric facts of this case and in the absence of any split in the circuits on the applicability of *Auer* in these circumstances.

In the first place, FDA has specifically disclaimed any interest in commenting on the issues in this lawsuit or influencing its outcome. GE requested testimony from FDA in this case but was flatly rejected in writing. FDA told GE that there were no "compelling circumstances" justifying agency participation in this case; that such participation would not be in the public interest; that it wants "to avoid the impression that FDA, or one of its employees, is taking a partisan position in litigation where, as here, the agency is not a party"; and that "the proposed testimony would not promote the objectives of the FFDCA." The agency's position not only suggests the inappropriateness of GE's reliance on the *Buckman* amicus brief but also

belies GE's hyperbolic invocations of health and safety concerns.

Second, GE's citation of *Auer* is off-target. In *Auer*, the agency whose regulations were squarely before the Court for interpretation in a concrete dispute was, again, specifically requested by the Court to give its views as amicus on the merits of the pending case. That is a far cry from GE's attempted utilization of an amicus brief from a different case raising completely different issues. *Buckman* involved a wholesale attempt to subject FDA's procedures to second-guessing by civil juries and threatened the primacy of the statutes under which FDA operates. In contrast, none of the agency's 510(k) machinery was even invoked in this business dispute between two private corporations. None of the agency's regulations have been interpreted in the present case, and petitioner is asking for a ruling on a hypothetical set of facts, *i.e.*, what would have happened if GE hadn't breached the Agreement? In any event, it is inappropriate to ascribe a viewpoint to FDA on completely different facts from those in *Buckman*, especially in light of its unequivocal refusal to participate in this case. The Eighth Circuit did not mention *Auer* or the FDA amicus brief in its opinion and did not err in refusing to apply *Auer*. But even assuming otherwise, no split in the circuits exists regarding how *Auer* should be applied to such a fact-intensive private dispute as is presented here.

Finally, even discounting the self-serving interest of a federal agency in expanding its jurisdiction, the *Buckman* amicus brief does not help GE. The FDA *Buckman* brief suggests that when a device is to be promoted *exclusively* for one use, that use must be disclosed by the manufacturer to FDA. Here, the only promotion of the 770 monitor referred to in the evidence

was for term use. FDA's analysis of "intended use" in the *Buckman* brief is mistaken because it is predicated on §801.4, which, as noted above, is a labeling regulation that does not apply to the 510(k) application process. *Bowen*, 172 F.3d at 687. And to the extent FDA claims the province of looking behind the statement of intended use to police off-label use, it runs afoul of § 360c(i)(1)(E)(i).

But even postulating the contrary for the sake of argument, (a) the Model 770 was not to be used exclusively for pre-term patients; (b) the amicus brief expressly disclaims "knowledge" as defining the need for identifying uses; (c) §801.4 permits the manufacturer to protect itself against the consequences of subsequent off-label use by "provid[ing] adequate labeling for such a device which accords with such other uses to which the article is to be put"; and (d) in any event, GE could have avoided breaching the Agreement by filing a 510(k) for term use of the 770 monitor while pursuing a PMA application or a reclassification petition for pre-term use on a separate track.

GE never contended at trial that the 770 monitor was to be used "exclusively" for pre-term patients but instead characterized pre-term as the "vastly predominant" use. The evidence showed that Biomedical monitors term as well as pre-term patients. Many of the patients Biomedical now serves with the AMS 510(k)-cleared monitor do indeed use them through term. It therefore would have been perfectly proper for GE to label and promote the intended use for the 770 as being for term patients as it contracted to do; indeed, such a statement could only be false if the device *could not* be used at all for term patients.

In sum, the FDA amicus brief in a different case raising completely different issues is too thin a reed

upon which to hang a request for review by this Court. Moreover, the FDA position, properly construed, does not undermine the conclusion reached by the two lower courts and the jury.

CONCLUSION

For the reasons stated, the petition for writ of certiorari should be denied.

Respectfully submitted,

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October 2002